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| 10/589,674 | 04/03/2007 | Markus Graf Matuschka-Greiffenclau | DEBE:068US/10609441 | 9938 |
| 32425 | 7590 | 03/10/2010 | EXAMINER | |
| FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701 | | | | MACAULEY, SHERIDAN R |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|-------------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/589,674 | MATUSCHKA-GREIFFENCLAU ET AL. | |
| | Examiner | Art Unit | |
| | SHERIDAN R. MACAULEY | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 November 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18 is/are rejected.
- 7) Claim(s) 18 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>5/31/2007</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 1-18 are pending.

Election/Restrictions

1. Applicant's election of claim 18 (Group II) in the reply filed on November 4, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement for restriction is still determined proper and is therefore made final.
2. Claims 1-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
3. Claim 18 is examined on the merits in this Office action.

Claim Objections

4. Claim 18 is objected to because of the following informalities. It is recommended that the claim be amended as follows: In the second line of the claim, the term "alcohol degrading process" should be preceded with the words "an", "the" or some appropriate article. In the fourth line of the claim, the word "supplementa" should be amended to "supplement", "supplemental", or some other appropriate term. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The claim is rendered indefinite by the recitation of "in the first place" at the end of the seventh line of the claim. The term is a relative term that is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what applicant means by "in the first place". For instance, it could mean prior to the consumption of alcohol, after the consumption of alcohol but before the formation of acetaldehyde or prior to acetaldehyde accumulation. Therefore, the metes and bounds of the claim would be unclear to one of ordinary skill in the art. Applicant is advised to remove of the term "in the first place" or to amend the claim to some other definite expression.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10. The claim recites a method of affecting alcohol degrading process in respect to ethanol metabolism within the human body, comprising administering to a subject the food composition or dietary supplements of claim 1 (a composition comprising the following substances in physiologically relevant amount: dextrose, vitamin C, L-glutamine, cysteine, riboflavin, succinic acid, and/or fumaric acid, and coenzyme Q10), wherein said method has the following effects within the human body: reducing ethanol metabolism by slowing down the process of ethanol oxidation into acetaldehyde, to prevent accumulation of acetaldehyde in the first place; stimulating the activity of ALDH and avoiding any blockade of its enzymatic activity; speeding up the reaction from acetaldehyde to acetic acid and further decomposition in the citrate cycle; and improving the levels of those anti-oxidants of the alcohol consumer which specially protect against toxic effects of acetaldehyde.

11. In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential

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that every factor be examined in detail, those factors deemed most relevant should be considered. In the instant case, those factors deemed most relevant are the amount of direction or guidance presented, the presence or absence of working examples and the nature of the invention.

12. The disclosure is not enabling for a method for affecting alcohol degrading processes in respect to ethanol metabolism in a human body, wherein the method has the effects recited in the claims, because it does not present enough direction and guidance for one skilled in the art to use the invention with a reasonable expectation of success without undue experimentation. The disclosure does not provide any guidance or working examples to direct one to perform the method recited in the claim on a human in order to achieve the result recited in the claims. The working examples disclosed in the instant application are directed to the formulation of the composition and the various benefits that the elements of the composition may provide. There are no working results directed to the actual administration of the composition recited in the claims to a human patient, and no evidence is provided to demonstrate that the various components of the composition would confer the benefits described in the claims when administered to a human patient, particularly in the combination recited in the claims. Further, the nature of the invention is such that a specific range of benefits would be expected as a result of the practice of the method. There are no findings in the specification to demonstrate that the results recited in the claims would occur upon administration of the composition of the claims. Given these facts, one skilled in the art

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would be unable to predict whether the claimed method could be performed with a reasonable expectation of success.

13. Therefore, the disclosure of the instant application does not enable one skilled in the art to practice the invention as claimed.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popp et al. (US 6,630,158; cited in prior action) and Amselem (US 5,989,583; cited in prior action). The claim recites a method of affecting alcohol degrading process in respect to ethanol metabolism within the human body, comprising administering to a subject the food composition or dietary supplements of claim 1 (a composition comprising the following substances in physiologically relevant amount: dextrose, vitamin C, L-glutamine, cysteine, riboflavin, succinic acid, and/or fumaric acid, and coenzyme Q10), wherein said method has the following effects within the human body: reducing ethanol metabolism by slowing down the process of ethanol oxidation into acetaldehyde, to prevent accumulation of acetaldehyde in the first place; stimulating the activity of ALDH and avoiding any blockade of its enzymatic activity; speeding up the reaction from acetaldehyde to acetic acid and further decomposition in the citrate cycle; and improving the levels of those anti-oxidants of the alcohol consumer which specially protect against toxic effects of acetaldehyde.

18. Popp teaches methods for the administration of supplements comprising dextrose (glucose), vitamin C, L-glutamine, cysteine, riboflavin and coenzyme Q-10 to humans (col. 3, lines 1-25 and 46-67, col. 7, lines 61-67). The reference does not teach the inclusion of succinic acid or fumaric acid in the compositions for use in the methods taught therein.

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19. Amselem teaches supplements comprising succinate and that succinate is a useful additive in compositions comprising coenzyme Q-10 to lessen oxidation of the compound (col. 6, line 62-col. 7, line 9).

20. At the time of the invention, the administration of a composition comprising nearly all of the claimed elements was known, as taught by Popp. The inclusion of succinate in a composition comprising coenzyme Q-10 in such a composition was also known, as taught by Amselem. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed method by including succinate in the composition of Popp because Amselem teaches that succinate is a useful additive in compositions comprising coenzyme Q-10 to lessen oxidation of the compound. Although the references do not teach the claimed effects on alcohol metabolism within the human body, since the compositions of the prior art contain all of the claimed elements, any effects of the claimed invention would be inherent to the method of the combined prior art. One of ordinary skill in the art would have had a reasonable expectation of success in performing the combined method because Popp teaches that the compositions are suitable for administration to humans and Amselem teaches that succinate is compatible with such a composition. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651